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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,840

01/05/2006

Yoshinobu Morimoto

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EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,840	<b>Applicant(s)</b> MORIMOTO ET AL.	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12, 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks filed on August 13, 2007 is acknowledged. Receipt of the Letter Requesting an Interview with the examiner is also acknowledged. Applicants Representative was contacted, however, due to time constraints, it was determined an interview was not needed at this time. It was suggested that after receiving this office action, if applicant would like an interview to discuss the case to telephone the examiner at 571-272-9039 and request an interview.

Claims 1-12 and 14 remain pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ancira et al. (US PGPub 2004/0137077).

Ancira discloses, a composition for the treatment of seborrheic keratosis comprising at least one melanin inhibitor. Examples of such melanin inhibitors include gamma-L-Cysteine and tranexamic acid" (paragraph 0034).

Ancira also teaches, "to aid in moisturizing or conditioning the skin, as will be known to those of skill in the art in view of the instant disclosure. For example, other ingredients may be added to improve the skin condition or the effectiveness of the compositions. Vitamins may be added to the compositions to aid in improving the skin condition thereby inhibiting the production of subsequent cutaneous anomalies after treatment of the original condition" (Ancira, paragraph 0063). Ancira further discloses the vitamin may be L-ascorbic acid (0032). Ancira discloses methods of seborrheic keratosis removal; the compositions are also effective in removing other skin conditions such as hyper pigmentation" (paragraph 0062). It is the examiners position that the removal of hyper pigmentation is the same as whitening the skin and treating pigmentations .

With regard to Claims 2, 4, 6, and 8, according to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382).

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Ancira discloses tranexamic acid and L-cysteine among hundreds or thousands of possible combinations. The examiner respectfully disagrees with Applicant's assessment of the number of melanin inhibitors disclosed, a review of the prior art reference discloses approximately 40 inhibitors. Therefore, it is the position of the examiner that 40 would be considered a finite group of options and therefore, well within the skill and knowledge of one of ordinary skill in the art to choose 2 from the disclosed list. Furthermore, according to MPEP, it has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). It is further noted that applicant has used the terminology comprising allowing the inclusion of any number of additional components. Applicant further argues the examiner has not provided motivation to combine the two melanin inhibitors claimed. The examiner respectfully disagrees. Ancira discloses "at least one" melanin inhibitors may be used. The fact that Ancira does not disclose the exact combination does not exclude the reference from teaching a combination from a finite grouping of components.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bundgaard et al. (US Patent 5,073,641).

Bundgaard discloses prodrugs of carboxylic acid agents which are capable of providing increased biomembrane transport so that the parent drugs are more bioavailable from the site of administration such as the gastro-intestinal tract, the rectum, the skin or the eye of the human body (column 3, lines 3-11). Bundgaard discloses the compounds disclosed include all diastereomers or enantiomers, or mixtures thereof (i.e. Examples of isomers are D-, L-, and DL- forms) (column 5, lines 16-18). Non-toxic pharmaceutically acceptable acid salts may be included such as ascorbic acid (column 5, lines 20-29). Suitable drugs to inclusion into the formulation include tranexamic acid (column 9, line 39) and L-cysteine (column 9, line 60). While the specific compounds are disclosed in a list of compounds suitable for use, it is the position of the examiner that the list constitutes a finite number of compounds and therefore, it would have been obvious to a person of ordinary skill in the art to select two of the disclosed bio-affecting carboxylic acid agents disclosed.

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of L-Cysteine or its derivatives thereof, all of which are known in the art to be used for

the same purpose. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iwasaki et al. (US 6,703,031).

Due to the new grounds of rejection presented in this office action, this again is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

/Michael P Woodward/  
Supervisory Patent Examiner, Art  
Unit 1615